**UNITED STATES DISTRICT COURT**
**DISTRICT OF MAINE**

| | |
|---|---|
| BRENDA SMITH,<br><br>Plaintiff,<br><br>v.<br><br>AROOSTOOK COUNTY and SHAWN D. GILLEN,<br><br>Defendants. | Docket No. 1:18-cv-00352-NT |

**MOTION OF MAINE MEDICAL ASSOCIATION *ET AL* FOR LEAVE TO FILE *AMICI CURIAE* BRIEF IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION**

As preeminent associations comprised of leaders in the fields of medicine, behavioral health, and addiction medicine, *Amici* respectfully seek leave to file the attached *Amici Curiae* brief ("Brief") in support of plaintiff's motion for a temporary restraining order and preliminary injunction.

*Amici* believe their expertise regarding the treatment of Opioid Use Disorder ("OUD") with medication-assisted therapy ("MAT") would provide the Court with detailed understanding of the state of research into the relative benefits and risks associated with various types of OUD treatment, including the scientific consensus on the efficacy of MAT maintenance programs versus the Defendants' current regimen.

*Amici* briefs are appropriate when the *Amici* have unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide. *See* Charles Alan Wright & Arthur R. Miller, FEDERAL PRACTICE AND PROCEDURE § 3975 (4th ed.). This Court has inherent authority to accept *amici*

submissions, and the Brief of these *Amici* meets these standards. *See, e.g., Verizon New England, Inc. v. Maine Pub. Utils. Comm'n*, 229 F.R.D. 335, 338 (D. Me. 2005).

Granting leave to file this Brief will not prejudice the defendants, as the results of evidence-based clinical research cannot, by nature, be prejudicial to the truth. Thus, based upon the insights these *Amici* are able to share, this Court should grant *Amici's* motion for leave to file their Brief.

Respectfully Submitted,

**MAINE MEDICAL ASSOCIATION ET AL**

By Their Attorneys,

*/s/ Richard L. O'Meara*
Richard L. O'Meara, Bar No. 3510
MURRAY, PLUMB & MURRAY
75 Pearl Street, P.O. Box 9785
Portland, ME 04104-5085
(207) 773-5651
romeara@mpmlaw.com

*/s/ Joel K. Goloskie*
Joel K. Goloskie (MA BBO# 675806)
Meagan L. Thomson (MA BBO#696711)
PANNONE LOPES DEVEREAUX & O'GARA LLC
One International Place, Suite 1400
Boston, MA 02110
Ph: 617.535.7724
Fax: 866.353.5020
jgoloskie@pldolaw.com
mthomson@pldolaw.com

**CERTIFICATE OF SERVICE**

I certify that on January 30, 2019, I electronically filed the foregoing Motion for Leave to File *Amici Curiae* Brief in Support of Plaintiffs' Motion for Preliminary Injunction with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

*/s/ Richard L. O'Meara*
Richard L. O'Meara

**UNITED STATES DISTRICT COURT**
**DISTRICT OF MAINE**

| | |
|---|---|
| BRENDA SMITH,<br><br>Plaintiff,<br><br>v.<br><br>AROOSTOOK COUNTY and SHAWN D. GILLEN,<br><br>Defendants. | Docket No. 1:18-cv-00352-NT |

**_AMICI CURIAE_ BRIEF OF MAINE MEDICAL ASSOCIATION _ET AL_ IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION**

**TABLE OF CONTENTS**

## INTRODUCTION

*Amici* are preeminent associations comprised of leaders in the fields of medicine, behavioral health, and addiction medicine. They have knowledge and expertise relevant to the interface of criminal justice and Opioid Use Disorder ("OUD"), and seek to educate the Court about the most current medical science and professional standards that inform the issues presently before this Court.

Our nation is gripped by an opioid epidemic that claimed more than 49,000 lives in 2017. Drug overdose is now the leading cause of death for those under 50. A disproportionately large percentage of incarcerated persons have opioid use disorder, many with a co-occurring mental illness. There is medical consensus that OUD is a chronic brain disease that is characterized by continued use of opioids despite negative consequences, and that ineffectively-treated OUD results in a high rate of relapse and overdose. Decades of research shows that Medication Assisted Treatment ("MAT") is the most effective treatment modality for OUD, and that opioid agonist maintenance therapy, using a medication such as methadone or buprenorphine, is far more effective at preventing relapse and saving lives than are withdrawal programs. Furthermore, there is no research supporting withdrawal or detoxification programs alone, especially those that do not include MAT (such as that run by the Defendants) as sufficient treatment for opioid use disorder.

Three FDA-approved drugs currently exist to provide MAT, and the current standard of research and clinical guidelines states that the most effective MAT modality varies from person to person. Accordingly, altering an individual's prescribed course of MAT for nonclinical reasons (including by substituting one medication for another) could result in the individual receiving substandard treatment, and thus facing an increased risk of relapse. Simply put, ceasing ongoing buprenorphine treatment and imposing the defendants' non-

MAT based, forced withdrawal program on this plaintiff is entirely contrary to the current research and clinical standards.

## STATEMENT OF INTEREST OF AMICI CURIAE

The **Maine Medical Association** ("MMA") is a professional association of more than 4,300 physicians, residents, and medical students in Maine, whose mission is to support Maine physicians, advance the quality of medicine in Maine, and promote the health of all Maine citizens. The MMA is Maine's largest physician professional organization and represents physicians in all medical specialties and practice settings. The MMA represents Maine in the federation of the American Medical Association ("AMA"). The MMA has a strong interest in this litigation because it has been actively engaged in policy advocacy and education about the Opioid Use Disorder crisis, including increasing access to medication-assisted treatment in Maine.

The ***Northern New England Society of Addiction Medicine*** ("NNESAM") is a statewide medical organization providing education, leadership, and support for physicians, trainees and allied health professionals in support of excellence in care of people with substance use disorders and of access to such care for all. NNESAM is a chapter of the American Society of Addiction Medicine, the flagship organization in the field of addiction medicine and the publisher of The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use.

The ***Maine Association of Psychiatric Physicians*** ("MAPP") is the Maine district branch of the American Psychiatric Association ("APA") and the only professional organization of psychiatry and psychiatrists dedicated to the State of Maine. Its mission is to improve the treatment, rehabilitation and care of persons with mental disorders, to provide leadership and to promote and advocate for the professional interests of its members and

patient care. The MAPP has a strong interest in this litigation because it has been actively engaged in policy advocacy and education about mental health in general and the Opioid Use Disorder crisis in particular, including increasing access to medication-assisted treatment in Maine.

## STATEMENT OF THE ISSUE

Whether a correctional facility's policies for patients with Opioid Use Disorder, which unilaterally impose a non-MAT, forced withdrawal program on all incarcerated individuals with Opioid Use Disorder, and which impose cessation of all existing MAT regimens, is commensurate with modern medical science and of a quality acceptable within prudent professional standards.

## SUMMARY OF THE ARGUMENT

There is consensus within the global medical community that OUD is a disease involving alteration of neural circuitry in the brain. There is medical consensus that the most effective treatment regimens for OUD include MAT, and there is incredibly robust data demonstrating the effectiveness of methadone maintenance programs in reducing mortality. As many persons with OUD fail to recover on originally-prescribed medications, there is also medical consensus that the most effective form of MAT varies from person to person.

While research shows that MAT-based withdrawal programs are largely ineffective in preventing relapse and are thus not within the standard of care for OUD treatment, no research has found non-MAT based withdrawal programs, like that operated by the defendants, to have any meaningful success in preventing relapse. Here, the defendants do not utilize any MAT during detoxification, instead adhering to an Opiate Withdrawal Protocol that includes an 11-day regime of Central Nervous System ("CNS") depressants,

thereby requiring the cessation of all existing MAT regimens upon entry to the facility. Patients do not leave the facility with additional medication, a referral to a physician providing MAT for their opioid use disorder, or even a prescription.

The Plaintiff has been in recovery for approximately 10 years. While she relapsed on initially prescribed MAT medications, she has remained in remission and recovery while on her currently-prescribed regimen of buprenorphine. This is consistent with the literature, which shows methadone and buprenorphine are first-line treatments that are proven to reduce mortality. In fact, the literature shows that the odds of relapse from the Defendants' type of Opiate Withdrawal Protocol, rather than allowing continuation of a clinically appropriate MAT such as buprenorphine, make it likely that the Plaintiff will relapse shortly after being released back into the community, if she does not do so even before leaving the correctional facility.

Accordingly, *Amici* believe that the Defendants' Opiate Withdrawal Protocol, which provides non-MAT detoxification, and which prohibits methadone or buprenorphine prescribing, places the Plaintiff at significant, unnecessary risk of relapse, and thus is not commensurate with modern medical science or of a quality acceptable within prudent professional standards.

## ARGUMENT

### I. Withdrawal Programs Lead to Avoidably High, Unacceptable Rates of Relapse, Overdose, and Death.

#### A. OUD is a Chronic Brain Disease.

Prevailing understandings of neuroscience continue to support the brain disease model of addiction.[1] In fact, the American Psychiatric Association's Diagnostic and

[1] Volkow et al., *Neurobiological Advances from the Brain Disease Model of Addiction*, *N Engl J Med* 2016;374:363-71.

Statistical Manual of Mental Disorders—the leading authority on mental disorders—states that "[a]n important characteristic of substance use disorders is an underlying change in brain circuits."[2] In the introductory page to a 2016 report on alcohol, drugs and health by the U.S. Surgeon General, no less than the Secretary of the U.S. Department of Health and Human Services states that "addiction is a chronic neurological disorder and needs to be treated as other chronic neurological conditions are."[3] OUD is similar to that of other chronic relapsing conditions such as diabetes and hypertension.[4]

**B. Detoxification-alone is a Dangerously Outdated Model.**

The clinical course of OUD involves periods of exacerbation and remission, but the underlying vulnerability never disappears.[5] The concept of an OUD sufferer "getting clean" by detoxication alone after a period of withdrawal is an outdated model, inconsistent with the current literature.[6] Accordingly, the underlying change in brain circuitry arising from OUD carries a grave risk of potentially-fatal relapse if ineffectively treated: the opioid epidemic, as noted, claimed an average of 115 lives per day in 2016.[7]

---

[2] *American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders (5th ed.)*, p. 483 (2013) (commonly referred to as the "DSM-5").

[3] U.S. Department of Health and Human Services. *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health, 2016*, Intro. by Secretary Sylvia Mathews Burwell, p. I, avail. at: https://www.surgeongeneral.gov/library/2016alcoholdrugshealth/index.html.

[4] Shukit MA. Treatment of opioid use disorders. *N Engl J Med* 2016; 375;4(357).

[5] *Id.* (citing O'Brien CP. Drug addiction. In: Brunton L, Chabner B, Knollman B, eds. Goodman & Gilman's the pharmalogical basis of therapeutics. 12th ed. New York: McGraw-Hill, 2011:649-66).

[6] *See Id.*

[7] Samet JH, Botticelli M, Bharel M. Methadone in primary care—one small step for Congress, one giant leap for addiction treatment. *N Engl J Med* 2018; 379;1:7.

### C. MAT-assisted Programs are Effective in Avoiding Relapse and Saving Lives.

MAT is an evidence-based approach to OUD treatment that focuses on medical therapy, in the form of an opioid agonist or antagonist, often combined with counseling and recovery support.[8] Decades of research have demonstrated the efficacy of medications such as methadone and buprenorphine in improving remission rates and reducing both medical complications and the likelihood of overdose death.[9]

Methadone and buprenorphine are opioid agonists: they substitute themselves for the more dangerous and addictive forms of opioids in a manner that helps the patient's re-wired brain avoid relapse. Opioid agonists are commonly used in both maintenance and detoxification purposes.[10] Antagonist medications, by contrast, reduce a OUD patient's "high" from opioid ingestion, and thus attempt to weaken the stimulus-reward mechanism leading to continued use.

### D. Maintenance Programs Save Lives While Withdrawal Programs are Largely Ineffective.

MAT maintenance programs are the current standard of care in the treatment of OUD. MAT maintenance programs provide a steady dose of methadone or buprenorphine, such that the patient can avoid the craving for illicit opioids and successfully engage with the activities of daily life. Maintenance programs using an agonist like methadone or buprenorphine have demonstrably better outcomes than withdrawal ("detox") programs for important patient-centered outcomes such as overdose death, rates of communicable disease,

---

[8] Dunlap B, Cifu AS. Clinical management of opioid use disorder. *JAMA Clinical Guidelines Synopsis. JAMA* Vol. 316, No. 3. (July 19, 2016).

[9] Wakeman SE, Barnett ML. Primary care and the opioid-overdose crisis – buprenorphine myths and realities. *N Engl J Med* 2018 379;1(1).

[10] Stotts AL, Dodrill CL, Kosten TR. Opioid dependence treatment: options in recovery. *Expert Opin Pharmacother*, 2009 Aug; 10(11):1727.

retention in treatment, and relapse.[11] Multiple studies of withdrawal programs demonstrate that the majority of patients relapse with withdrawal management alone, even with tapering with opioid agonist medications to alleviate withdrawal symptoms.[12] One 2010 prospective cohort study of 109 patients discharged from residential detoxification treatment showed that 91% of patients relapsed, with 59% relapsing in the first week.[13]

## II. The Defendants' Non-MAT Withdrawal Program is Not Commensurate with Modern Medical Science or Prudent Professional Standards.

### A. The Defendants Ignore the Potential Deleterious Effects of Providing Inmates with Benzodiazepine.

#### i. The Defendants' Program in Insufficiently Matched to Individual Needs.

All persons actively suffering or recovering from OUD who enter incarceration by the Defendants receive the same, one-size-fits-all Opiate Withdrawal Protocol. This is true regardless of whether these individuals: 1) are on a prescribed MAT maintenance regimen when they present for incarceration, 2) are successfully avoiding relapse on that prescribed regime, or 3) have relapsed on other prescribed regimes in the past.

The U.S. Surgeon General's 2016 report cited above states that "[t]he treatment plan and goals should be person-centered and include strength-based approaches." "Tailoring treatment to the patient's specific needs increases the likelihood of successful treatment." "[T]he research clearly demonstrates that opioid antagonist therapy leads to better treatment

---

[11] Dunlap B, Cifu, AS. Clinical management of opioid use disorder. *JAMA Clinical Guidelines Synopsis. JAMA* Vol. 316, No. 3. (July 19, 2016) (citing Mattick RP, Breen C,Kimber J, Davoli M. Buprenorphine maintenance vs placebo or methadone maintenance for opioid dependence. *Cochrane Database Syst Rev.* 2014;(2):CD002207; also citing MacArthur GJ, Minozzi S, Martin N, et al. Opiate substitution treatment and HIV transmission in people who inject drugs. *BMJ* 2012;345(3:e5945-e5945).

[12] *Id.*

[13] *Id.* (citing Smyth BP, Barry J, Keenan E, Ducray K. Lapse and relapse following inpatient treatment of opioid dependence. *Ir Med J.* 2010;103(6):176-179.

outcomes compared to behavioral treatments alone."

The National Institutes of Health's National Institute on Drug Abuse, in its online publication entitled Principles of Drug Abuse Treatment for Criminal Justice Populations—A Research-Based Guide, advises correctional facilities that "[o]ne of the goals of treatment planning is to match evidence-based interventions to individual needs at every stage of drug treatment." "[T]he effectiveness of drug treatment depends on both the individual and the program, and on whether interventions and treatment services are available and appropriate for the individual's needs."

NIH also advises correctional facilities that "[w]hile individuals progress through drug abuse treatment at different rates, one of the most reliable findings in treatment research is that lasting reductions in criminal activity and drug abuse are related to length of treatment. Generally, better outcomes are associated with treatment that lasts longer than 90 days, with treatment completers achieving the greatest reductions in drug abuse and criminal behavior." The Defendants' Opiate Withdrawal Protocol is discontinued after a maximum of 11 days: far less than the ninety-day minimum advised by the NIH.

An article in the American Medical Association's AMA Journal of Ethics reinforces the dangers of forcibly withdrawing stable patients from an opioid agonist therapy. As twelve percent of jail inmates report using opioids regularly (compared to a reported non-medical use by 1.8 percent of non-incarcerated persons), a program that ignores a patient's success on agonist maintenance therapy and forcibly withdraws stable patients is by all standards ethically concerning, and in many cases may prove life-threatening.

Importantly, the consensus of the literature does not support the use of benzodiazepines, such as Lorazepam, for opioid withdrawal. Although benzodiazepines continue to be the mainstay of treatment in alcohol withdrawal, providing highly significant

reduction in seizures and delirium,[14] the same outcomes are not consistently found in the treatment of opioid withdrawal. The Defendants have provided no research or information to support their implementation of titrated benzodiazepine treatment for inmates experiencing opioid withdrawal.

The Defendants' Opiate Withdrawal Protocol ignores respect for patient autonomy, limits access to evidence-based care, and results in negative outcomes for individuals, communities, and society. In light of the scientific evidence, withholding effective medical treatment with opioid agonist therapy from people with addiction is ethically questionable in any context. To do so during a public health crisis that disproportionately affects incarcerated persons is unconscionable.

**ii. Benzodiazepines are Highly Addictive.**

The Defendants contend that their Opiate Withdrawal Protocol—which only purports to treat some *symptoms* of opioid withdrawal as opposed to the underlying addiction and cravings—is sufficient treatment for all inmates experiencing withdrawal. Specifically, the Defendants contend that all inmates are assessed for the risk of opiate withdrawal symptoms using the "widely-accepted" Clinical Opiate Withdrawal Scale ("COWS"). If an inmate scores high enough on the COWS, they are provided a titrated prescription of Lorazepam over an 11-day period to alleviate symptoms of withdrawal, specifically anxiety.

Lorazepam is a benzodiazepine, a type of prescription sedative commonly prescribed for anxiety or to help with insomnia.[15] Benzodiazepines work to calm or sedate a person, by

[14] Chad A. Asplund, MD, Jacob W. Aaronson, DO, Hadassah E. Aaronson, DO, *3 Regimens for alcohol withdrawal and detoxification*, J Fam Pract. 2004 July;53(7):545-554, https://www.mdedge.com/jfponline/article/65531/addiction-medicine/3-regimens-alcohol-withdrawal-and-detoxification/page/0/1#bib14.

[15] National Institute on Drug Abuse, *Benzodiazepines and Opioids*,(revised March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids.

raising the level of the inhibitory neurotransmitter GABA in the brain.[16] However, benzodiazepine has been found to be highly addictive, and can lead to severe withdrawal.[17] There is a growing concern that the overprescribing and overconsumption of benzodiazepines is a "hidden epidemic" in the United States.[18] Between 1996 and 2013, the number of adults who filled a benzodiazepine prescription increased by 67 percent, from 8.1 million to 13.5 million.[19] Through their established Opioid Withdrawal Protocol that incorporates benzodiazepines, the Defendants are denying inmates MAT medication proven to aid in long term opioid recovery, while simultaneously introducing an equally—if not more so—addictive and dangerous drug that has not been shown to benefit individuals experiencing opioid withdrawal. Such practices cannot reasonably be considered commensurate with modern medical science or prudent professional standards.

### B. The Defendants' Opiate Withdrawal Practices Directly Contradict Recommendations and Guidance Provided by the FDA.

The Defendants' Opiate Withdrawal Protocol is in *direct conflict* with the recommendations and guidance issued by the FDA, which suggest that the opioid addiction medications buprenorphine and methadone should not be withheld from patients taking benzodiazepines. In August 2016, the U.S. Food and Drug Administration ("FDA") issued a Drug Safety Communication in which they warned about the combined use of opioid-containing pain or cough medicines with benzodiazepines or other CNS depressants, and

---

[16] *Id.*

[17] Schumann, John Henning, *Benzodiazepines: America's 'Other Prescription Drug Problem,'* National Public Radio, Inc., (Apr. 26, 2018), https://www.npr.org/sections/health-shots/2018/04/26/602213172/benzodiazepines-america-s-other-prescription-drug-problem

[18] Anna Lembke, M.D., Jennifer Papac, M.D., and Keith Humphreys, Ph.D., *Our Other Prescription Drug Problem*, N Engl J Med 2018; 378:693-695.

[19] *Id.*

indicated that they would continue to evaluate the evidence regarding combined use of benzodiazepines or other CNS depressants with MAT drugs.[20] Subsequently, the FDA released an additional Drug Safety Communication which unequivocally advised that the opioid addiction medications buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system ("CNS").[21] The report provides in relevant part:

> [T]he U.S. Food and Drug Administration (FDA) is advising that the opioid addiction medications buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS). The combined use of [buprenorphine and benzodiazepines] increases the risk of serious side effects; however, ***the harm caused by untreated opioid addiction can outweigh these risks.*** Careful medication management by health care professionals can reduce these risks. (emphasis added)
>
> . . .
>
> Buprenorphine and methadone help people reduce or stop their abuse of opioids, including prescription pain medications and heroin. Methadone and buprenorphine have been shown to be effective in reducing the negative health effects and deaths associated with opioid addiction and dependency. These medications are often used in combination with counseling and behavioral therapies, and patients can be treated with them indefinitely. Buprenorphine and methadone work by acting on the same parts of the brain as the opioid that the patient is addicted to. The patient taking the medication as directed generally does not feel high, and withdrawal does not occur. Buprenorphine and methadone also help reduce cravings.
>
> . . .
>
> Health care professionals should … [recognize] that ***patients may require MAT medications indefinitely and their use should continue for as long as patients are benefitting*** and their use contributes to the intended treatment goals.[22] (Emphasis added).

---

[20] U.S. Department of Health and Human Services, *FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning*, U.S. Food & Drug Administration, (Aug. 31, 2016), https://www.fda.gov/Drugs/DrugSafety/ucm518473.htm.

[21] U.S. Department of Health and Human Services, *FDA Drug Safety Communication: FDA urges caution about withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants: careful medication management can reduce risks*, (Sept. 20, 2017), https://www.fda.gov/Drugs/DrugSafety/ucm575307.htm.

The FDA Commissioner further acknowledged that MAT "is one of the major pillars of the federal response to the opioid epidemic in this country."[23] The Defendants' Opiate Withdrawal Protocol ignores the FDA's recommendations by prescribing patients in withdrawal a titrated dose of benzodiazepines while simultaneously denying inmates access to prescribed MAT medications. The Defendants' Opiate Withdrawal Protocol is in direct conflict with the evidence-based recommendations of the FDA, and as such, cannot be considered commensurate with modern medical science or prudent professional standards.

### C. Substantial Deference Should Not Extend to Programs Contrary to Modern Medical Science or Prudent Professional Standards.

Given that the literature demonstrates that withdrawal programs are largely ineffective in avoiding potentially-fatal relapse even when MAT-based, the defendant's *non*-MAT based, one-size-fits-all program certainly must fail the test for substantial deference. It is insufficiently "commensurate with modern medical science [to be] of a quality acceptable within prudent professional standards," to quote the test for prison-based medical services articulated by the U.S. Circuit Court of Appeals for the First Circuit in *United States v. Derbes*.[24]

The *Derbes* decision was further clarified in the Eighth Amendment context in *Kosilek v. Spencer*, which reinforced that the adequacy of medical care is "measured against 'prudent professional standards.'"[25] The Defendants contend that the jail's decision not to

---

[22] *Id.*

[23] Knopf, Alison, *FDA: Keep Patients on Methadone or Buprenorphine, Even if They Test Positive for Benzodiazepines*, Addiction Treatment Forum, (Dec. 13, 2017), http://atforum.com/2017/12/fda-methadone-buprenorphine-benzodiazepines/

[24] *United States v. Derbes*, 369 F.3d 579, 583 (1st Cir. 2004) (citations and quotations omitted)).

[25] *Kosilek v. Spencer*, 774 F.3d 63, 83, 104 (1st Cir. 2014) (quoting *Nunes v. Massachusetts Dept. of Correction*, 766 F.3d 136, 142 (1st Cir. 2014) (quoting *U.S. v. DeCologero*, 821 F.2d 39, 43 (1st Cir. 1987)); see also *Leavitt v. Corr. Med. Servs., Inc.*, 645 F.3d 484, 497 (1st Cir. 2011).

provide opioid replacement mediation is adequate and entitled to deference.[26] However, the research cited herein makes it clear that the Defendants' program falls unacceptably short of the modern medical science and prudent professional standards required of prison-based medical treatment by *United States v. Derbes* and its progeny.

## CONCLUSION

The literature demonstrates that withdrawal programs are largely ineffective, even when MAT-based. At present, over nine out of ten participants in MAT-based withdrawal programs experience relapse, with over half relapsing in the first week. Given that no research has shown *non*-MAT based programs to be effective, and given that the literature overwhelmingly holds that treatment programs must be individually tailored to be effective, these *Amici* can state with a certainty appropriate to their positions in the international medical and scientific communities that the Defendants' non-MAT based, one-size-fits-all withdrawal program will result in needless episodes of relapse, overdose, and death. In addition, the Defendant's policy of ceasing medically-indicated MAT for treatment of OUD represents yet another deviation from the medical standard of care.

The sweep of substantial deference cannot include programs that fall below the current state of the science and professional standards, and thus must be limited to treatment regimens that the literature shows to have a reasonable probability of success. Based upon the well-vetted research showing that even MAT-based Withdrawal protocols lead to relapse in ninety percent of cases, as well as the FDA-issued Drug Safety Communications which specifically highlight the harms associated with titrating benzodiazepines while withholding

[26] DEFENDANTS AROOSTOOK COUNTY AND GILLEN'S PRELIMINARY OBJECTION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION (citing Kosilek v. Spencer, 774 F.3d 63, 83 (1st Cir. 2014)) ("When evaluating medical care and deliberate indifference, security considerations inherent in the functioning of a penological institution must be given significant weight.").

opioid addiction medications, *Amici* advise this Court that the Defendants' program is not at all "commensurate with modern medical science [or] of a quality acceptable within prudent professional standards,"[27] such that it fails the test for deference by this Court.

Accordingly, in the interest of preventing potentially-fatal relapse and overdose, the Defendants should be ordered to continue the Plaintiff's buprenorphine maintenance program for the duration of her brief forty-day incarceration.

Respectfully Submitted,

**MAINE MEDICAL ASSOCIATION ET AL**

By Their Attorneys,

*/s/ Richard L. O'Meara*
Richard L. O'Meara, Bar No. 3510
MURRAY, PLUMB & MURRAY
75 Pearl Street, P.O. Box 9785
Portland, ME 04104-5085
(207) 773-5651
*romeara@mpmlaw.com*

*/s/ Joel K. Goloskie*
Joel K. Goloskie (MA BBO# 675806)
Meagan L. Thomson (MA BBO#696711)
Pannone Lopes Devereaux & O'Gara LLC
One International Place, Suite 1400
Boston, MA 02110
Ph: 617.535.7724
Fax: 866.353.5020
jgoloskie@pldolaw.com
mthomson@pldolaw.com

[27] *Derbes*, 369 F.3d at 583.

**CERTIFICATE OF SERVICE**

I certify that on _____, 2019, I electronically filed the foregoing *Amici Curiae* Brief in Support of Plaintiffs' Motion for Preliminary Injunction with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

_____
Richard L. O'Meara